

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

**PETITION UNDER 37 C.F.R. §§1.47(b)  
and 1.42**

Docket Number:  
1662/460041  
(formerly 11701/46007)

Application Number  
10/657,737

Filing Date  
September 3, 2003

Examiner  
Not Yet Assigned

Art Unit  
1614

Invention Title  
PHARMACEUTICALLY ACCEPTABLE  
COMPOSITION COMPRISING AN AQUEOUS  
SOLUTION OF PACLITAXEL AND ALBUMIN

Inventor(s)  
KADIMA et al.

Address to:

Mail Stop Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited  
with the United States Postal Service with sufficient postage  
as first class mail in an envelope addressed to:  
Mail Stop Missing Parts, Commissioner for Patents, P.O.  
Box 1450, Alexandria, VA 22313-1450 on

Date: 5/19/04 Reg. No. 46,877

Signature: [Signature]

SIR:

In response to the Notice to File Missing Parts of Application mailed November 26, 2003 Attorney for Applicants, Tenshuk A. KADIMA, Howard A. KAPLAN and Robert C. TUTTLE, hereby petitions the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 hereby makes application for patent on behalf of and as agent for all the inventors. This petition includes proof of the pertinent facts showing that such action is necessary to preserve the rights of and to prevent irreparable damage to the parties.

The above-identified application is a continuation of U.S. Patent Application Serial No. 10/293,426, filed November 12, 2002, which is a continuation of Serial No. 09/947,420, filed September 5, 2001, which is a continuation of Serial No. 09/744,827 which is a 371 of PCT/US99/17179, filed July 29, 1999, which International Application claims the benefit of provisional application Serial No. 60/094,687, filed July 30, 1998.

The International Application was filed in the name of Novopharm Biotech, Inc. as Applicant for all designated States except the United States (Exhibit A). The inventors, Tenshuk KADIMA, Howard KAPLAN and Robert C. Tuttle, were listed as the applicants for

the United States. See attached copy of first page of published PCT application (Exhibit A).

Novopharm Biotech, Inc. assigned all of its rights in the international and national applications to Human RT in January 2001 (Exhibit B). A change of Applicant was filed with the International Bureau of WIPO on January 26, 2001 along with a Power of Attorney from Human RT appointing Dr. jur. Eva Somfai as Agent for Applicant (Exhibit C).

On January 26, 2001 Dr. Somfai (Human RT's foreign patent counsel) requested Kenyon & Kenyon (Human RT's U. S. patent counsel) to enter the national phase in the United States of PCT/US99/17179. Copies of January 26, 2001 order letter and Information Sheet for New Patent Application are attached (Exhibit D).

On January 26, 2001, Dr. Eva Somfai filed with the International Bureau a Rule 92bis letter requesting the addition of inventors, Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO (Exhibit E).

On April 26, 2001 Kenyon & Kenyon sent a letter to Dr. Somfai sending copies of the application as filed, Declaration and Assignment forms for signing by the inventors three (3) originally-named inventors and a Power of Attorney form for signing by the Assignee, Human RT. Reminder letters were sent to Dr. Somfai on June 29, 2001 and August 30, 2001.

Despite many attempts, Kenyon & Kenyon was unable to contact the three inventors, as did the foreign patent counsel. On July 9, 2003, letters were sent by Kenyon & Kenyon to the three originally-named inventors by Registered Mail, Return Receipt Requested to their last known addresses as follows:

Tenshuk A. Kadima  
7 Woodington Bay  
Winnipeg, Manitoba, Canada R3P 1M6

Howard A. Kaplan  
18 Hillhouse Road  
Winnipeg, Manitoba, Canada R2V 2V9

Robert C. Tuttle  
782 Allegheny Drive  
Winnipeg, Manitoba, Canada R3T 5L2

The letters included copies of the application as filed and a Declaration form for signing and returning to Kenyon & Kenyon. Copies of the letters are attached (Exhibit F).

The letter addressed to Mr. Kadima was returned as unclaimed (Exhibit G).

The letter addressed to Mr. Tuttle was returned as "address incomplete" by the Canadian Postal Service (Exhibit H). The address used was the only address listed in the International Publication Number WO 00/06152 of PCT/US99/17179. We attempted to obtain address for the inventors through Lexis and Westlaw, but without success (Exhibit I).

We learned that one of the inventors, Dr. Howard Kaplan, was deceased. We contacted the attorney for the heir of Dr. Kaplan, Mr. Randall Gray of Pitblado Buchwald Asper, Manitoba, Canada. Mr. Gray referred us to Mr. Robert A. Watchman of that firm to resolve the matter. Mr. Gray, after discussing the matter with Mr. Kaplan's heir, Ms. Carole Grad, advised us by letter dated March 22, 2004 (Exhibit J) that Ms. Grad cannot sign the Declaration as worded, because she cannot declare that she has reviewed and understands the content of the specification, including the claims, among other things. (As the sister of the inventor, she does not have the scientific background to understand the invention.)

Accordingly, despite our diligent efforts to contact the originally-named inventors to obtain a signed Declaration, we were unable to obtain signatures from the three inventors. We therefore respectfully petition the Commissioner under 37 C.F.R. §§1.47(b) and 1.42 to make application for patent on behalf of and as agent for all the inventors and Human RT, assignee of PCT/US99/17179.

In view of the foregoing, Applicants respectfully request that this Petition be granted under these specific facts.

Applicants also respectfully request that the following four (4) additional inventors be added to this application:.

After resolution of the 37 C.F.R. §§1.47(b) and 1.42 issues, Applicants will submit formal documents to add the above-mentioned additional four inventors to this application. These inventors (Lajos HEGEDUS, Krisztina KREMPELS, Krisztina PAAL and Gabor PETHO) have been previously included in the PCT (see Exhibit E).

A copy of the Notice to File Missing Parts of Application is also enclosed.

Applicants respectfully request a four-month extension of time to respond to the Notice to File Missing Parts of Nonprovisional Application, Filing Date Granted, for which a response period expiring on January 26, 2004 was set. The extended period expires on May 26, 2004.

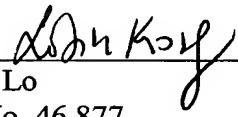
The Commissioner is hereby authorized to charge payment of the following fees to the deposit account of **Kenyon & Kenyon, No. 11-0600**:

- 1) Basic Filing Fee of \$770.00;
- 2) Additional claims fee of \$1,106.00;
- 3) 37 C.F.R. §1.17(i) petition fee of \$130.00;
- 4) 37 C.F.R. § 1.136(a) extension fee of **\$1,480.00**; and
- 5) 37 C.F.R. § 1.116(e) surcharge of \$130.00.

The Commissioner is also authorized to charge any additional fees and credit any overpayment in connection with this communication to the deposit account of Kenyon & Kenyon, No. 11-0600. A copy of this communication is enclosed herewith for charging purposes.

Respectfully submitted,

Dated: 5/19/04

By   
Siu K. Lo  
Reg. No. 46,877

KENYON & KENYON  
One Broadway  
New York, New York 10004  
Tel: (212) 425-7200  
Fax: (212) 425-5288

CUSTOMER NUMBER 26646

PCT

EXHIBIT A

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

P-0112

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>7</sup>:</b> A61K 31/337, 47/48, 47/42	<b>A1</b>	<b>(11) International Publication Number:</b> WO 00/06152 <b>(43) International Publication Date:</b> 10 February 2000 (10.02.00)
<b>(21) International Application Number:</b> PCT/US99/17179 <b>(22) International Filing Date:</b> 29 July 1999 (29.07.99) <b>(30) Priority Data:</b> 60/094,687 30 July 1998 (30.07.98) US <b>(71) Applicant (for all designated States except US):</b> NOVOPHARM BIOTECH, INC. [CA/CA]; 30 Novopharm Court, Toronto, Ontario M1B 2K9 (CA). <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> KADIMA, Tenshuk, A. [CA/CA]; 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6 (CA). KAPLAN, Howard, A. [CA/CA]; 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9 (CA). TUTTLE, Robert, C. [US/CA]; 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 (CA). <b>(74) Agents:</b> WU, Frank et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).		<b>(81) Designated States:</b> AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
<b>(54) Title:</b> PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN  <b>(57) Abstract</b>  An optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, serum albumin and a pharmaceutically acceptable vehicle, wherein the composition comprises no more than 10 % organic solvent and has a pH of about 3.0 to about 4.8, is described. The serum albumin can be fatted or defatted, and the composition can optionally be lyophilized or optionally lyophilized and reconstituted. At least 70 % of the paclitaxel is bound to serum albumin, the ratio of paclitaxel to albumin is at least about 1:5, and the concentration of paclitaxel is at least about 25 µg/ml. Methods of making and using this composition are also provided.		

# EXHIBIT B

## ASSIGNMENT

We, the undersigned Assignor

Novopharm Biotech Inc.  
30, Novopharm Court  
Toronto, Ontario, M1B 2K9 Canada

declare to have assigned our exclusive rights related to  
patent applications/patents enlisted below on

HUMAN RT.  
Tancsics M.u.82.  
H-2100 Gödöllő, Hungary

We also agree that this assignment be endorsed in the  
register of all international or national patent  
authorities.

Data of the patent application:

Number: PCT/US99/17179  
Title: "Pharmaceutically Acceptable Composition  
Comprising an Aqueous Solution of Paclitaxel  
and Albumin"  
Priority: US 60/094687 30. July 1998

For the Assignor:

Date:  
Toronto, January 2001

Signed by:

Capacity: MICHAEL A. BYRNE  
CHIEF FINANCIAL OFFICER

For the Assignee:

Date:  
Gödöllő, January 2001

Signed by:  
Lajos Hegedüs

Capacity:  
General manager

P-0112

**HUMAN**  
SERUM PRODUCTION AND  
MEDICINE MANUFACTURING  
COMPANY LIMITED BY SHARES  
Tancsics M. u. 82.  
Gödöllő, Hungary  
2100

SOMFAI & PARTNERS.

H-1137 Budapest, Pozsonyi út 38

Hungary

Tel: (361)3495-298

Fax: (361)3502-623

X Special Delivery

○ Air mail ○ Registered

○ Express

X Also by fax: 1 page(s) + 1

Nº: 00 41 22 740.14.35

Your letter:

Your ref: PCT/US99/17179

My ref: P-0112PCT

Please quote on all  
correspondence!

EXHIBIT C

INTERNATIONAL BUREAU OF WIPO  
34, chemin des Colombettes  
1211 Geneva 20  
SWITZERLAND

**URGENT!**

Budapest, 26. January 2001

F235,236/01sé

Re:	<b>Registration of Assignment of Application</b>	
PCT Application:	PCT/US99/17179 29. 07. 1999	
PCT Publication:	WO 00/06152	10. 02. 2000
Priority:	30. 07. 1998	US 60/094687

1. The patent application in caption and all rights related thereto were assigned from the original PCT applicant Novopharm Biotech Inc., 30. Novopharm Court, Toronto, Ontario M1B 2K9, Canada.

2. Data of the present applicant and the signatory:

**Assignee:**

HUMAN Rt.  
Táncsis út 82.  
H-2100 Gödöllő,  
Hungary

**Signatory:**

Lajos HEGEDŰS  
managing director

3. Please register the above change according to PCT Rule 92/bis at your earliest convenience. The 30 months (Chapter II) period expires on 30. January 2001.


4. Please find enclosed the

- Power of attorney signed by the new applicant appointing me to represent this application.

1 page \*

Thank you for your co-operation.

Respectfully



Dr. Eva Somfai  
patent attorney

Enclosure:

\*\* Fax and Mail: New Power of Attorney

Fax and Mail: Assignment Deed (follows on receipt)

P-0112

1/1

**MEGHATA MAZÁS**

Alulírott

**HUMAN RT;**  
Gödöllő, Hungaryezennel meghatalmazzuk(zom) a  
**SOMFAI és TÁRSAI**  
Iparjogi Kft-tSzabadalmi ügyvivő:  
Dr jur. Somfai Éva  
vegyésszmérnökhogyan az  
US 60/094687  
PCT/US99/17179  
-ra alapított,Pharmaceutically Acceptable Composition  
Comprising an Aqueous Solution of  
Paclitaxel and Albumin

című szabadalom és/vagy bejelentés

ügyben az illetékes hatóságok, bíróságok  
és hivatalok előtt teljes jogkörrel  
képviseljen.

Kelt/Date:

Név (Cég)/ Name (Firm):

HUMAN RT.

Cím/Address:

Táncsics M.u.82.

H-2100 Gödöllő, Hungary

Aláírás(ok)/ Signature(s)::

L. Hegedűs  
Managing Director

Name and capacity of signatories

**POWER**

The undersigned

**HUMAN RT;**  
Gödöllő, Hungaryhereby appoint(s)  
**SOMFAI and PARTNERS**  
Industrial Rights Co. Ltd.Patent Attorney:  
Dr jur. Eva Somfai  
eng. chem.  
concerning  
Patent and/or Application entitledPharmaceutically Acceptable Composition  
Comprising an Aqueous Solution of Paclitaxel  
and AlbuminN°  
based on  
US 60/094687  
PCT/US99/17179with full power of substitution and  
representation before the competent  
authorities, courts or offices.

(no legalization is required)

P-0112



**SOMFAI & PARTNERS**

Industrial Rights Co.Ltd.

H-1137 Budapest

Hungary

MAN  
RT

11701 - 46001

Tel:(361)3495-298

Fax:(361)3502-623

EXHIBIT D

X Special Delivery

o Air mail o Registered

o Express

X Also by fax: 3+6 page(s)

Nº: 00 1 212 425 5288

Your letter: -

Law Office Kenyon & Kenyon

One Broadway

NEW YORK N.Y. 10004-1050

U.S.A.

X

**URGENT!**

**IMPORTANT!**

Budapest, 26. January 2001

F231, 232/01kj

Attention of Mr. Steven J. Lee! and/or

Mr. Patrick Bird!

**PRIVILEGED AND CONFIDENTIAL!**

Dear Colleagues,

Re: New Patent Application in US of  
HUMAN RT "NOVBIO" based on US 60/094687  
PCT/US99/17179  
My ref: P-0112 US Please quote!  
Your ref: -  
**NATIONAL APPLICATION TO BE FILED in US**

Please

☐ File a new patent application in Canada

☒ Enter the national phase of the PCT application in caption.

To be filed: On/before **30. January 2001**

☐ 12 months priority

☐ 20 months PCT

☒ **30 months PCT date.**

If it is possible to file within 31 months in your country please file timely before the due date.

Documents:	Now enclosed	Follows	Please inform	Remarks
Information sheet	X 2 pages			fax
PCT Publication cover	X 1 page			fax
Specification to be filed	see PCT publ			• 125 pages
Claims to be filed	see PCT publ			• 4 pages

Figures to be filed	see PCT publ			• 28 pages
Abstract	see PCT publ			• 1 page
Power			X	
Inventors decl.			X	
Transfer of rights			X	
Data of newly added inventors	X 1 page			• •
Priority document			X	
PCT Search Report				•
PCT Publication				•
Change of representation and owner filed at WIPO	X 1 page			
Completion of inventor's list filed at WIPO	X 2 pages			
Acceptance by WIPO			X	

- is already in your file (5934/2)
- If you consider it would be better not to file this please
  - ☐ call me before filing any time between 9 and 19 our time
  - ☒ add the names when appropriate.

**Please indicate by return fax what else you need.** The outstanding documents will follow always with a copy of this letter.

We ask you to send the **filled-in Powers** and all other documents you need in the form **ready for signature**. Empty formulars will not be signed.

- ☒ The priority document was filed in English by the inventors Kadima Tenshuk, Kaplan Howard, Tuttle Robert C.
- ☒ The PCT application was filed by the assignor Novopharm Biotech, CA the prosecution was in English and the application was recently assigned. When writing this order letter the WIPO-registration of both the Assignment and completion of the list of inventors is still pending.

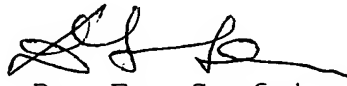
We await your debit notes in duplicate clearly indicating where and how you wish us to settle the same.

Please do not abandon this application if not expressedly instructed to do so.

Please confirm receipt both of the faxed and the mail version of this order letter as well as the documents by fax.

Thanking you for your immediate attention and looking forward to have a good co-operation.

Sincerely yours



Dr. Eva Somfai  
chem. ing. patent attorney

Enclosure:

Fax:	6 page(s)
Air mail:	- page(s)
Spec. delivery	6 page(s)

**INFORMATION SHEET FOR NEW PATENT APPLICATION**

**TITLE:** Pharmaceutically Acceptable Composition  
Comprising an Aqueous Solution of  
Paclitaxel and Albumin

**APPLICANT:** HUMAN RT  
Táncsics M.u.82.  
H-2100 Gödöllő, Hungary

**PRIORITY:** 30.07.1998 US 60/094687

**PCT APPLICATION:** PCT/US99/17179 29.07.1999

**PCT PUBLICATION:** WO 00/06152 10.02.2000

**INVENTOR(S):** Kadima, Tenshuk  
Kaplan, Howard  
Tuttle, Robert C.  
Dr. Hegedűs, Lajos  
Dr. Krempels, Krisztina  
Dr. Paál, Krisztina  
Dr. Pethő, Gábor

TO BE  
ADDED  
WHEN  
APPROPRIATE

To be filed: On/before **30. January 2001**

- ☐ 12 months priority
- ☐ 20 months PCT
- ☒ 30 months PCT date.

If it is possible to file within 31 months in your country please file timely before the due date.

**ASSIGNMENTS:**

- ☒ The priority application was filed by:  
Inventors Kadima, Kaplan, Tuttle (CA)  
all of Novopharm Biotech, CA.
- ☒ The PCT application was filed by:  
Novopharm Biotech, CA, ~~except~~ in the US where it  
was filed by inventors Kadima, Kaplan, Tuttle.
- ☒ The application was assigned on HUMAN RT., HU  
registration of the change was requested in the  
international phase on 26.01.2001

- ☒ The national application has to be filed in the name of HUMAN RT., HU alone.  
The assignment documents will follow as soon as available.
- ☒ Because important subject matter of the claimed invention was based on the invention of the four Hungarian inventors now appearing in the list of inventors - registration of completion of the inventor's list was requested on 26.01.2001 at the WIPO.

H-1137 Budapest, Pozsony 138  
Hungary

X Special Delivery  
O Air mail O Registered  
O Express

X Also by fax: 1 page(s)

Nº: 00 41 22 740.14.35

Your letter:

Your ref: PCT/US99/17179

My ref: P-0112PCT

**URGENT!** F237,238/01sé

TEL. (361) 3475-270  
FAX: (361) 3502-623

EXHIBITE

INTERNATIONAL BUREAU OF WIPO  
34, chemin des Colombettes  
1211 Geneva 20  
SWITZERLAND

Budapest, 26. January 2001

Re: **Registration of Change in Person of Inventors**  
PCT Application: PCT/US99/17179 29.07.1999  
Priority: 30. 07. 1998 US 60/094687

1. Reverting to my letter earlier this day I hereby ask to register the following further change according to PCT Rule 92/*bis* at your earliest convenience. The 30 months (Chapter II) period expires on 30. January 2001.
2. Because important subject matter of the claimed invention was based on the invention of authors whose names did not appear in the list of inventors as originally filed, the Applicant completed the list of inventors by adding of the following persons:
  - i) DR. HEGEDŰS, Lajos; chemical engineer;  
Hungarian citizen;  
Eötvös út 47  
H-1121, Budapest, Hungary
  - ii) DR. KREMPELS, Krisztina; physician; Hungarian  
citizen; Ady E. út 204  
H-1188 Budapest, Hungary
  - iii) DR. PAÁL, Krisztina; chemist, Hungarian citizen;  
Felsőzöldmáli út 80  
H-1025 Budapest, Hungary
  - iv) DR. PETHŐ, Gábor; pharmacist; Hungarian citizen;  
Kassai út 10  
H-1225, Budapest, Hungary

Thank you for your co-operation and help.

Respectfully

  
Dr. Eva Somfai  
patent attorney

EXHIBIT F

July 9, 2003

**VIA REGISTERED MAIL -  
Return Receipt Requested**

Mr. Tenshuk A. Kadima  
7 Woodington Bay  
Winnipeg, Manitoba  
Canada R3P 1M6

Re: U. S. Patent Application Serial No. 10/293,426  
PHARMACEUTICALLY ACCEPTABLE COMPOSITION  
COMPRISING AN AQUEOUS SOLUTION OF  
PACLITAXEL AND ALBUMIN  
Our Ref: 11701/46003

Dear Mr. Kadima:

We are contacting you on behalf of our client, Human RT.

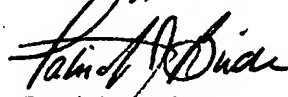
As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,

  
Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)  
Steven J. Lee, Esq. (w/o enc.)

July 9, 2003

**VIA REGISTERED MAIL -**  
**Return Receipt Requested**

Mr. Robert C. Tuttle  
782 Allegheny Drive  
Winnipeg, Manitoba  
CANADA R3T 5L2

Re: U. S. Patent Application Serial No. 10/293,426  
PHARMACEUTICALLY ACCEPTABLE COMPOSITION  
COMPRISING AN AQUEOUS SOLUTION OF  
PACLITAXEL AND ALBUMIN  
Our Ref: 11701/ 46003

Dear Mr. Tuttle:

We are contacting you on behalf of our client, Human RT.

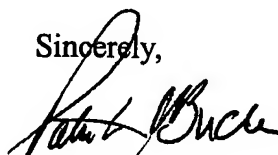
As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

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Sincerely,

  
Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)  
Steven J. Lee, Esq. (w/o enc.)



July 9, 2003

**VIA REGISTERED MAIL -  
Return Receipt Requested**

Mr. Howard A. Kaplan  
18 Hillhouse Road  
Winnipeg, Manitoba  
CANADA R2V 2V9

Re: U. S. Patent Application Serial No. 10/293,426  
PHARMACEUTICALLY ACCEPTABLE COMPOSITION  
COMPRISING AN AQUEOUS SOLUTION OF  
PACLITAXEL AND ALBUMIN  
Our Ref: 11701/ 46003

Dear Mr. Kaplan:

We are contacting you on behalf of our client, Human RT.

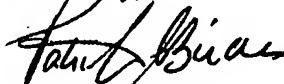
As you may recall, Human RT purchased the rights to the above-referenced invention from Novopharm Biotech Inc. A patent application has been filed in the United States and has been assigned Serial No. 10/293,426. In order to complete the filing requirements for the application, we are now required to file a Declaration signed by all the inventors. A Declaration form is enclosed along with a copy of the application as filed in the United States Patent Office for your review.

Please sign and date the Declaration form where indicated and return the signed form to us as soon as possible. A postage paid DHL return envelope is enclosed for your convenience in returning the form.

If we do not hear from you within two (2) weeks from the date of this letter, we will assume you are unwilling to sign the form and will proceed accordingly.

Please feel free to contact myself (212-908-6452) or Mary Werner (212-908-6183) or in writing if you have any questions in this matter.

Sincerely,



Patrick J. Birde

Enclosures

cc: Dr. Eva Somfai (w/o enc.)  
Steven J. Lee, Esq. (w/o enc.)

BEST AVAILABLE COPY

NEW YORK, N. Y. 10004

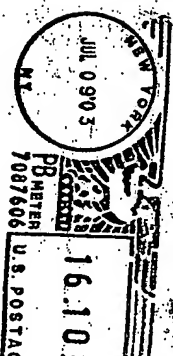
EXHIBIT

G

To: Patrick J. Binde  
7th Floor

Unclassified  
EO 12812-2  
8/1/99

RECEIVED  
NEW YORK  
JUL 13 1999  
KENYON & KENYON



KENYON  
KENYON  
Intellectual Property Law

Broadway  
New York, NY 10004-1050

Mr. Tenshuk A. Kadima  
7 Woodington Bay  
Winnipeg, Manitoba, CANADA R3P 1M6

TURN TO SENDER  
NO A L'EXPEDITEUR

Checklist for return to sender:

- ☐ Undelivered
- ☐ Non delivered
- ☐ No such address
- ☐ Addressee unavailable
- ☐ Address incomplete
- ☐ Addressee deceased
- ☐ Moved
- ☐ Denied
- ☐ No such Post Office
- ☐ Bureau not open
- ☐ Refused by addressee
- ☐ Refused per the destination

RETURN TO SENDER  
RENOI A L'EXPEDITEUR

- ☒ Undelivered
- ☐ No such address
- ☐ Addressee unavailable
- ☐ Address incomplete
- ☐ Addressee deceased
- ☐ Moved
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- ☐ No such Post Office
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- ☐ Refused per the destination



CANADA POST  
GRANT PARK POSTAL OUTLET  
3941 12th Avenue  
Winnipeg, MB R2M 2B9

Return Receipt for International Mail  
(Registered, Insured, Recorded Delivery, Express Mail)

UNITED STATES POSTAL SERVICE

Par Avion

Kenyon & Kenyon  
ATTORNEYS AT LAW  
NEW YORK, N.Y. 10004

UNITED STATES OF AMERICA

AVIS de réception

2865 February 1997

RS 505 899 905 US

102595 99-M-1904

EXHIBIT H

133

2003-07-13

BUREAU DE POSTE - TORONTO

ADDRESSE INCOMPLETE // ADRESSE INCOMPLETE  
RETURN TO SENDER  
RENOUVEAU A L'EXPEDITEUR  
NY 10004

Mr. Robert C. Tuttle  
782 Allegheny Drive  
Winnipeg  
Manitoba CANADA R3T 5L2

*addressee incomplete*

*Due*

One Broadway  
New York, NY 10004-1050

**IK KENYON**  
Intellectual Property Law

NY 0903

1545

U.S. POSTAGE

BEST AVAILABLE COPY

Werner, Mary

(T)  
EXHIBIT I

**From:** Werner, Mary  
**Sent:** Friday, August 01, 2003 2:03 PM  
**To:** Butler, Timothy  
**Subject:** RE: 11701/46001 - for Tuesday

Thanks, Tim.

-----Original Message-----

**From:** Butler, Timothy  
**Sent:** Friday, August 01, 2003 2:01 PM  
**To:** Werner, Mary  
**Subject:** RE: 11701/46001 - for Tuesday

Mary

It turns out that they can only obtain this information for people in the US. I'm going to hold on to this and try Westlaw next week. This was the answer which I received from your Lexis representative.

-----Original Message-----

**From:** Werner, Mary  
**Sent:** Thursday, July 24, 2003 6:36 PM  
**To:** Butler, Timothy  
**Subject:** 11701/46001 - for Tuesday

Tim,

These are the inventors in Canada for whom we need updated addresses:

KADIMA, Tenshuk, A., 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6, CA 02

KAPLAN, Howard, A., 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9, CA 03

TUTTLE, Robert, C., 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 / CA 04

Thanks.

Mary

**Werner, Mary**

---

**From:** Butler, Timothy  
**Sent:** Wednesday, August 06, 2003 7:22 PM  
**To:** Werner, Mary  
**Subject:** RE: 11701/46001 - for Tuesday

Mary  
I tried again with West law . sorry no results

-----Original Message-----

**From:** Werner, Mary  
**Sent:** Thursday, July 24, 2003 6:36 PM  
**To:** Butler, Timothy  
**Subject:** 11701/46001 - for Tuesday

Tim,

These are the inventors in Canada for whom we need updated addresses:

KADIMA, Tenshuk, A., 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6, CA 02

KAPLAN, Howard, A., 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9, CA 03

TUTTLE, Robert, C., 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 / CA 04

Thanks.

Mary

**PITBLADO**  
ARRISTERS & SOLICITORS

EXHIBIT J

2500 - 360 Main Street  
Winnipeg, Manitoba  
Canada R3C 4H6

Tel. (204) 956 0560  
Fax (204) 957 0227  
E-mail firm@pitblado.com

Reply to:  
**Robert A. Watchman**  
Direct (204) 956 3568  
watchman@pitblado.com

VIA TELECOPIER 212-425-5288

March 22, 2004

Kenyon & Kenyon  
One Broadway  
New York, NY 10004-1050

Attention: **Slu K. Lo**

Dear Sir:

Re: **U.S. Patent Application Serial No. 10/293,426**  
**Your Reference: 1662/46003**

This will acknowledge receipt of your letter dated March 11, 2004 enclosing documentation with respect to the above-noted application.

As you may recall in our telephone conversation of September 3, 2003, because of the particular wording of the inventor's declaration for the United States, the representative of Dr. Kaplan's estate cannot sign the declaration. That is, the wording requires her to declare, under threat of penalty, that she has reviewed and understands the content of the specification, including the claims, amongst other things.

We wish to emphasize that Ms. Grad does not wish to appear to be uncooperative and she is not disputing the application or your client's entitlement to the invention, it is simply that she cannot sign the declaration as worded.

In our telephone discussion, I referred to other patent applications in which the same issue arose in which the applicant proceeded on the basis that the representative "refuses" to sign the declaration, which I believe is provided for in 37 CFR 1.42.

In our September 3, 2003 telephone conversation, you indicated that you believe the rules might have provided for some variation when the documents were to be signed by a representative. However, unless there is some other wording for the declaration, the representative of Dr. Kaplan's estate will not be able to sign.

Yours very truly,

**PITBLADO**

per: *Robert A. Watchman*  
**Robert A. Watchman**  
RAW:dew